

CLAIMS:

Sub B1
1. An isolated 125P5C8-related protein.

2. The 125P5C8-related protein of claim 1, wherein the 125P5C8-related protein has at
5 least 6 contiguous amino acids of an amino acid sequence shown in SEQ ID NO: 2.

3. The 125P5C8-related protein of claim 1, wherein 125P5C8-related protein has at
least 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, or more than 25 contiguous
amino acids of an amino acid sequence shown in SEQ ID NO: 2.

4. The 125P5C8-related protein of claim 1, wherein the 125P5C8-related protein is at
10 least 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 85, 90, 95, 100 or more than 100 contiguous amino acids of
an amino acid sequence shown in SEQ ID NO: 2.

5. The 125P5C8-related protein of claim 1, wherein the 125P5C8-related protein
includes an amino acid sequence selected from the group consisting of amino acid residues 1-23, 40-
43, 42-64, 79-84, 94-116, 94-145, 99-104, 118-160, 120-142, 122-137, 152-154, 170-173, 174-194,
15 175-178, 189-211, 199-204, 238-260, 242-284, 268-273, 269-291, 287-292, 309-314, 318-340, 319-
373, 341-346, 350-368, 380-383, 381-383, 389-391, 389-391, 390-411, 445-448, 455-458, 457-460,
463-466, 496-498, 536-539, 538-540, 606-609, 610-617, 629-632, 634-637, 644-652, 666-668, 666-
668, and 677-680, of SEQ ID NO: 2.

6. An 125P5C8-related protein of claim 1 that comprises an HLA class I A1, A2, A3,
20 A24, B7, B27, B58, B62 supermotif, or an HLA class II DR supermotif set forth in Table IV (B) or an
Alexander pan DR binding epitope supermotif or an HLA DR3 motif.

7. An 125P5C8-related protein of claim 1 that comprises at least one conservative
substitution.

8. An 125P5C8-related protein of of claim 1 that comprises an epitope that induces a
25 specific antibody response.

9. The 125P5C8-related protein of claim 8, wherein the 125P5C8-related protein
includes an amino acid sequence selected from the group consisting of amino acid residues 65-93, 143-
188, 261-268, 341-349, and 412-699 of SEQ ID NO: 2

10. The 125P5C8-related protein of claim 8, wherein the 125P5C8-related protein includes an amino acid sequence selected from the group consisting of amino acid residues 24-41, 117-119, 212-237, 292-317, and 369-389 of SEQ ID NO: 2

5 11. The 125P5C8-related protein of claim 1, wherein the 125P5C8-related protein has the amino acid sequence shown in SEQ ID NO: 2

12. The 125P5C8-related protein that is at least 90% homologous to an amino acid sequence of claim 1.

13. The 125P5C8-related protein that is at least 90% identical to an amino acid sequence of claim 1.

10 14. An isolated 125P5C8-related protein of claim 1 that has an amino acid sequence which is exactly that of an amino acid sequence encoded by a polynucleotide selected from the group consisting of:

(a) a polynucleotide consisting of the sequence as shown in SEQ ID NO: 1, wherein T can also be U;

15 (b) a polynucleotide consisting of the sequence as shown in SEQ ID NO: 1, from nucleotide residue number 82 through nucleotide residue number 696, wherein T can also be U;

(c) a polynucleotide that encodes a 125P5C8-related protein whose sequence is encoded by the cDNAs contained in the plasmids designated [***] deposited with American Type Culture Collection as Accession No. PTA-[***];

(d) a polynucleotide that encodes an 125P5C8-related protein that is at least 90% homologous to the entire amino acid sequence shown in SEQ ID NO: 2;

(e) a polynucleotide that encodes an 125P5C8-related protein that is at least 90% identical to the entire amino acid sequence shown in SEQ ID NO: 2;

25 (f) a polynucleotide that is fully complementary to a polynucleotide of any one of (a)-(e); and,

(g) a polynucleotide that selectively hybridizes under stringent conditions to a polynucleotide of (a)-(e).

15. An 125P5C8 nucleotide, where T can be U, that comprises:
- (a) a polynucleotide having the sequence as shown in Figure 2 (SEQ ID NO: 1), from nucleotide residue number 1 through nucleotide residue number 2103; or,
 - (b) a polynucleotide having the sequence as shown in Figure 2 (SEQ ID NO: 1), from nucleotide residue number 1 through nucleotide residue number 2100; or,
 - (c) a polynucleotide having the sequence as shown in Figure 2 (SEQ ID NO: 1), from nucleotide residue number 1 through nucleotide residue number 2097; or
 - (d) a polynucleotide of at least 10 bases of Figure 2 (SEQ ID NO: 1) that comprises the base at position 339;
 - (e) a polynucleotide of at least 10 bases of Figure 2 (SEQ ID NO: 1) that comprises the base at position 1119;
 - (f) a polynucleotide of at least 10 bases of Figure 2 (SEQ ID NO: 1) that comprises the base at position 2065;
 - (g) a polynucleotide that selectively hybridizes under stringent conditions to a polynucleotide of (a)-(f);
- wherein a range is understood to specifically disclose all whole unit positions thereof.

16. A polynucleotide of claim 15 that encodes a 125P5C8-related protein, wherein the polynucleotide is a polynucleotide consisting of the sequence as shown in Figure 2 (SEQ ID NO: 1), from nucleotide residue number 82 through nucleotide residue number 696, wherein T can also be U.

17. A polynucleotide of claim 15 that encodes a 125P5C8-related protein, wherein the polypeptide includes an amino acid sequence selected from the group consisting of amino acid residues 1-23, 40-43, 42-64, 79-84, 94-116, 94-145, 99-104, 118-160, 120-142, 122-137, 152-154, 170-173, 174-194, 175-178, 189-211, 199-204, 238-260, 242-284, 268-273, 269-291, 287-292, 309-314, 318-340, 319-373, 341-346, 350-368, 380-383, 381-383, 389-391, 389-391, 390-411, 445-448, 455-458, 457-460, 463-466, 496-498, 536-539, 538-540, 606-609, 610-617, 629-632, 634-637, 644-652, 666-668, 666-668, and 677-680, of SEQ ID NO: 2.

18. A polynucleotide of claim 15 that encodes an 125P5C8-related protein, wherein the protein comprises an HLA class I A1, A2, A3, A24, B7, B27, B58, B62 supermotif, or an HLA class II DR supermotif set forth in Table IV (B) or an Alexander pan DR binding epitope supermotif or an HLA DR3 motif.

19. A polynucleotide of claim 15 that is labeled with a detectable marker.

20. A recombinant expression vector that contains a polynucleotide of claim 15.

21. A host cell that contains an expression vector of claim 20.

22. A process for producing a 125P5C8-related protein comprising culturing a host cell of claim 21 under conditions sufficient for the production of the polypeptide and recovering the 125P5C8-related protein so produced.

5 *Arb*
C77 23. A 125P5C8-related protein produced by the process of claim 22.

24. An antibody or fragment thereof that specifically binds to a 125P5C8-related protein.
25. The antibody or fragment thereof of claim 24, that specifically binds to a portion of the 125P5C8-related protein, wherein the portion is selected from the group consisting of amino acid residues 65-93, 143-188, 261-268, 341-349, and 412-699 of SEQ ID NO: 2.
- 5 26. The antibody or fragment thereof of claim 24, that specifically binds to a portion of the 125P5C8-related protein, wherein the portion is selected from the group consisting of amino acid residues 24-41, 117-119, 212-237, 292-317, and 369-389 of SEQ ID NO: 2.
27. The antibody or fragment thereof of claim 24, which is monoclonal.
28. A recombinant protein comprising the antigen-binding region of a monoclonal
10 antibody of claim 27.
29. The antibody or fragment thereof of claim 24, which is labeled with a detectable marker.
30. The recombinant protein of claim 28, which is labeled with a detectable marker.
31. The antibody fragment of claim 24, which is an Fab, F(ab')₂, Fv or Sfv fragment.
- 15 32. The antibody of claim 24, which is a human antibody.
33. The recombinant protein of claim 28, which comprises murine antigen binding region residues and human constant region residues.
34. A non-human transgenic animal that produces an antibody of claim 24.
35. A hybridoma that produces an antibody of claim 27.
- 20 36. A single chain monoclonal antibody that comprises the variable domains of the heavy and light chains of a monoclonal antibody of claim 27.
37. A vector comprising a polynucleotide that encodes a single chain monoclonal antibody of claim 36 that immunospecifically binds to a 125P5C8-related protein.

38. An assay for detecting the presence of a 125P5C8-related protein or polynucleotide in a biological sample comprising steps of

contacting the sample with an antibody or another polynucleotide, respectively, that specifically binds to the 125P5C8-related protein or polynucleotide, respectively; and,

5 detecting the binding of 125P5C8-related protein or polynucleotide, respectively, in the sample thereto.

39. An assay of claim 32 for detecting the presence of an 125P5C8-related protein or polynucleotide comprising the steps of:

obtaining a sample,

10 evaluating said sample in the presence of an 125P5C8-related protein or polynucleotide, whereby said evaluating step produces a result that indicates the presence or amount of 125P5C8-related protein or polynucleotide, respectively.

40. An assay of claim 39 for detecting the presence of an 125P5C8 polynucleotide in a biological sample, comprising:

15 (a) contacting the sample with a polynucleotide probe that specifically hybridizes to a polynucleotide encoding an 125P5C8-related protein having an amino acid sequence shown in Figure 2; and

(b) detecting the presence of a hybridization complex formed by the hybridization of the probe with 125P5C8 polynucleotide in the sample, wherein the presence of the hybridization
20 complex indicates the presence of 125P5C8 polynucleotide within the sample.

41. An assay for detecting the presence of 125P5C8 mRNA in a biological sample comprising:

(a) producing cDNA from the sample by reverse transcription using at least one primer;

5 (b) amplifying the cDNA so produced using 125P5C8 polynucleotides as sense and antisense primers to amplify 125P5C8 cDNAs therein, wherein the 125P5C8 polynucleotides used as the sense and antisense probes are capable of amplifying the 125P5C8 cDNA contained within the plasmid as deposited with American Type Culture Collection as Accession No. PTA-
[***];

(c) detecting the presence of the amplified 125P5C8 cDNA,

10 42. A method for monitoring 125P5C8 gene products comprising:

determining the status of 125P5C8 gene products expressed by cells in a tissue sample from an individual;

comparing the status so determined to the status of 125P5C8 gene products in a corresponding normal sample; and

15 identifying the presence of aberrant 125P5C8 gene products in the sample relative to the normal sample.

20 43. A method of monitoring the presence of cancer in an individual comprising:
performing the method of claim 42 whereby the presence of elevated 125P5C8 mRNA or protein expression in the test sample relative to the normal tissue sample provides an indication of the presence or status of a cancer.

44. The method of claim 43, wherein the cancer occurs in a tissue set forth in Table I.

45. A pharmaceutical composition comprising a substance that modulates the status of a cell that expresses 125P5C8.

46. A pharmaceutical composition of claim 45 that comprises an 125P5C8-related protein and a physiologically acceptable carrier.

5 47. A pharmaceutical composition of claim 45 that comprises an antibody or fragment thereof that specifically binds to a 125P5C8-related protein and a physiologically acceptable carrier.

48. A pharmaceutical composition of claim 45 that comprises a polynucleotide that encodes a single chain monoclonal antibody that immunospecifically binds to an 125P5C8-related protein and a physiologically acceptable carrier.

10 49. A pharmaceutical composition of claim 45 that comprises a polynucleotide comprising a 125P5C8-related protein coding sequence and a physiologically acceptable carrier.

50. A pharmaceutical composition of claim 45 that comprises an antisense polynucleotide complementary to a polynucleotide having a 125P5C8 coding sequence and a physiologically acceptable carrier.

15 51. A pharmaceutical composition of claim 45 that comprises a ribozyme capable of cleaving a polynucleotide having 125P5C8 coding sequence and a physiologically acceptable carrier.

52. A method of treating a patient with a cancer that expresses 125P5C8, the method comprising steps of:

20 administering to said patient a vector that comprises the composition of claim 48, such that the vector delivers the single chain monoclonal antibody coding sequence to the cancer cells and the encoded single chain antibody is expressed intracellularly therein.

53. A method of inhibiting in a patient the development of a cancer that expresses 125P5C8, the method comprising:

administering to the patient an effective amount of the composition of claim 45.

25 54. A method of generating a mammalian immune response directed to 125P5C8, the method comprising:

exposing the mammal's immune system to an immunogenic portion of an 125P5C8-related protein of claim 1 or a nucleotide sequence that encodes said protein, whereby an immune response is generated to 125P5C8.

55. A method of delivering a cytotoxic agent to a cell that expresses 125P5C8, said
5 method comprising:

conjugating the cytotoxic agent to an antibody or fragment thereof of claim 24 that specifically binds to a 125P5C8 epitope; and,

exposing the cell to the antibody-agent conjugate.

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56. A method of inducing an immune response to an 125P5C8 protein, said method comprising:

providing a 125P5C8-related protein of claim 1 that comprises at least one T cell or at least one B cell epitope;

5 contacting the epitope with an immune system T cell or B cell respectively, whereby the immune system T cell or B cell is induced.

57. The method of claim 56, wherein the immune system cell is a B cell, whereby the induced B cell generates antibodies that specifically bind to the 125P5C8-related protein.

58. The method of claim 57, wherein the immune system cell is a T cell that is a cytotoxic T cell (CTL), whereby the activated CTL kills an autologous cell that expresses the 125P5C8 protein.

59. The method of claim 56, wherein the immune system cell is a T cell that is a helper T cell (HTL), whereby the activated HTL secretes cytokines that facilitate the cytotoxic activity of a CTL or the antibody producing activity of a B cell.